**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| Appellant(s) | : | Andrea MARINELLO and Vittorio MARINELLO |
| Serial No. | : | 10/662,775 |
| For | : | APPARATUS FOR THE INTRODUCTION OF A NEW SYSTEM FOR THE TREATMENT OF MAXILLARY AND FRONTAL SINUSITIS AND NEURITIS AND NEURALGIA OF THE TRIGEMINAL NERVE |
| Filed | : | September 15, 2003 |
| Examiner | : | Isis A. Ghali |
| Art Unit | : | 1615 |
| Confirmation No. | : | 2185 |

July 19, 2010

745 Fifth Avenue
New York, NY 10151

**APPEAL BRIEF AND PETITION FOR A TWO-MONTH EXTENSION OF TIME**

**Mail Stop APPEAL BRIEF - PATENTS**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an appeal from the Final Rejection by the Examiner dated February 19, 2010, which issued in the above-identified application, finally rejecting claims 13-30. A Notice of Appeal is concurrently being filed and accompanied by the requisite fee of $270.00 for a small entity as set forth in 37 C.F.R. § 41.20.

## PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136, a two-month extension of the period for reply, i.e. up to and including July 19, 2010, is respectfully requested. A check for $245.00 in payment of the fee for a small entity under 37 C.F.R. § 1.17(a) is enclosed. The Commissioner is authorized to charge any additional fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

## REAL PARTY IN INTEREST

The real parties in interest are Applicants Andrea Marinello, Via G. Zamboni 38/A, 37131 Verona, Italy and Vittoria Marinello, Via G. Zamboni 38/A, 37131 Verona, Italy.

## RELATED APPEALS AND INTERFERENCES

Upon information and belief, the undersigned attorney does not believe that there is any appeal or interference that will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

## REQUEST FOR AN ORAL HEARING

An oral hearing is not requested at this time but Appellants reserve the right to timely request one in accordance with 37 C.F.R 41.47(b).

## STATUS OF THE CLAIMS

The Application was filed with claims 1-33 on September 15, 2003, and assigned Application Serial No. 10/662,775.

In a first Office Action dated September 6, 2006, a restriction requirement was made, requiring election of one invention as found in Group I (claims 1-12), Group II (claims 13-30), Group III (claims 31-32), or Group IV (claim 33). In response, Appellants elected Group II, claims 13-30, drawn to a device comprising a facial mask, an inflatable elastic pad, and compress containing a cress having an active agent to promote the absorption of the active agent to the sinus and a method of its use to treat sinusitis.

In the first Office Action on the merits dated December 26, 2006, the Examiner rejected claims 13-30 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement; § 112, second paragraph, for indefiniteness; and § 112, second paragraph, as being incomplete for omitting essential elements. Claims 13, 15-25, and 27-30 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 2,262,711 to Ludwin ("Ludwin") in view of U.S. Patent No. 4,193,401 to Marinello ("Marinello '401"). Claims 14 and 26 were rejected under § 103(a) as unpatentable over Ludwin in view of U.S. Patent No. 5,248,504 to Friedman ("Friedman").

Appellants filed a response amending claims 13, 19, 24, and 25, and traversing the § 112 rejections.

The Examiner then issued a Final Office Action on June 29, 2007, rejecting claims 13-30 under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. Claims 13, 15-25, and 27-30 were rejected as unpatentable over Ludwin in view of Marinello '401. Claims 14 and 26 were rejected under § 103(a) as unpatentable over Ludwin in view of U.S. Patent No. 5,248,504 to Friedman ("Friedman").

In response to the Final Office Action, Appellants submitted an amendment on September 27, 2007, amending claims 13, 19, and 25 and traversing the rejections.

A Notice of Non-compliant Amendment was mailed on October 15, 2010, noting a formality. In response, Appellants corrected the formality and re-presented the response on October 25, 2007.

The Examiner issued an Advisory Action on November 1, 2007, indicating that the amendments in the October 25, 2007 response would not be entered. A Request for Continued Examination was submitted on November 28, 2007.

The Examiner issued a non-final Office Action on March 3, 2008 which did not mention the § 112 rejections, tacitly acknowledging that they have been overcome. Claims 13, 15-25, and 27-30 were rejected under 35 U.S.C. § 103(a) as unpatentable over Ludwin in view of Marinello '401. Claims 14 and 26 were rejected under § 103(a) as unpatentable over Ludwin in view of Friedman.

Appellants submitted a response on August 4, 2008 traversing the § 103 arguments.

The Examiner issued a Final Office Action on November 13, 2008, rejecting claims 13, 15-25, and 27-30 under 35 U.S.C. § 103(a) as unpatentable over Ludwin in view of Marinello '401. Claims 14 and 26 were rejected under § 103(a) as unpatentable over Ludwin in view of Friedman.

On April 29, 2009, Appellants submitted a Pre-Appeal Brief Request for Review in response to the November 13, 2008 final Office Action.

A Notice of Panel Decision was mailed on May 22, 2009 withdrawing the Final Office Action and reopening prosecution.

The Examiner issued an Office Action on August 21, 2009 rejecting claim 21 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Claims 13-14, 17-19, 21-26, and 30 were rejected under 35 U.S.C. § 103(a) as unpatentable over GB 2088714 to Marinello ("Marinello"), Ludwin, and U.S. Patent No. 6,748,949 to Smaldone ("Smaldone"). Claims 15, 16, 27, and 28 were rejected under § 103(a) as unpatentable over Marinello with Ludwin and Smaldone, in view of *Flavor pharmaceutical properties of the volatile sulphur compounds of Wasabi* by Depree et al. ("Depree"). Claims 20 and 29 were rejected under § 103(a) as unpatentable over Marinello with Ludwin and Smaldone in view of U.S. Patent No. 5,429,126 to Bracken ("Bracken").

A response was filed on November 23, 2009, traversing the rejections presented.

The Examiner issued a Final Office Action ("the Office Action") on February 19, 2010 rejecting claims 13-14, 17-19, 21-26, and 30 under 35 U.S.C. § 103(a) as unpatentable over Marinello, Ludwin and Smaldone. Claims 15, 16, 27, and 28 were rejected under § 103(a) as unpatentable over Marinello with Ludwin and Smaldone, in view of Depree. Claims 20 and 29

were rejected under § 103(a) as unpatentable over Marinello with Ludwin and Smaldone in view of Bracken.

This Appeal Brief is being filed along with a Notice of Appeal.

Accordingly, the status of the claims may be summarized as follows:

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|---|---|
| Claims Canceled: | None |
| Claims Allowed: | None |
| Claims Rejected: | 13-30 |
| Claims Withdrawn: | 1-12 and 31-33 |
| Claims Objected To: | None |

Rejected claims 13-30 are set forth in the Appendix attached hereto. Appellants are appealing the Final rejections of claims 13-30, which constitute all of the currently pending claims in this application.

## STATUS OF THE AMENDMENTS

Appellants submit that no amendments have been filed subsequent to the final rejection.

Accordingly Appellants believe that all the submitted Amendments have been entered.

## SUMMARY OF THE CLAIMED SUBJECT MATTER

The citation to locations in the original Figures and Specification are provided immediately following elements of each of the claims which Appellants summarize below. However, such citations are merely examples and are not intended to limit the interpretation of the claims or to evidence or create any estoppel.

Claim 13 recites a device comprising a facial mask, an inflatable elastic pad, and a compress comprising a revulsive having an active ingredient. (Page 5, lines 4-6; Figs. 1-2, refs. 10, 110.) The mask is configured to allow unobstructed respiratory function of the nostrils and mouth. (Page 6, lines 30-32.) The device promotes absorption of the active ingredient through the skin to bones underlying mucous membranes in the sinuses of a person. (Page 6, lines 19-23.)

Claim 14 recites the device of claim 13 wherein the active ingredient is allyl isothiocyanate. (Page 7, lines 13-14.)

Claim 15 recites the device of claim 13 wherein the compress is soaked in water to activate the active ingredient. (Page 7, lines 1-22.)

Claim 16 recites the device of claim 15 wherein the water is at a temperature of approximately 10°C. (Page 7, line 15.)

Claim 17 recites the device of claim 13 wherein the inflatable pad includes a first and a second membrane. (Page 7, lines 4-6.)

Claim 18 recites the device of claim 17 wherein the first and second membranes form a compression chamber. (Page 7, line 6.)

Claim 19 recites the device of claim 18 wherein a rubber pump is used to inflate the inflatable elastic pad. (Page 7, lines 8-10.)

Claim 20 recites the device of claim 13 wherein the facial mask comprises at least one opening and a means for securing the device to a person's head. (Page 6, lines 29-33.)

Claim 21 recites the device of claim 13 wherein the mask covers an upper portion of a person's head. (Page 6, lines 28-29 and Figs. 2, 4, 6, 8, and 12.)

Claim 22 recites the device of claim 13 wherein the mask covers the lower portion of a person's head. (Page 6, lines 28-29 and Figs. 1, 3, 5, 7, and 12.)

Claim 23 recites the device of claim 13 wherein the facial mask is adapted to allow respiration. (Page 6, lines 30-32 and page 8, lines 30-31.)

Claim 24 recites the device of claim 13 wherein the facial mask is made of plastic resistant to deformation. (Page 6, lines 26-27 and page 8, lines 31-32.)

Claim 25 recites a method of treating sinusitis comprising the steps of securing to a persons head a device comprising a facial mask (Page 5, lines 12-13; Figs. 1 and 2) accommodated to allow unobstructed respiratory function of the nostrils and mouth (Page 6, lines 30-32), an inflatable elastic pad and a compress fitted to the elastic pad, the compress comprising a revulsive or cress having an active ingredient (page 6, lines 23-25), the device promoting absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus. (Page 6, lines 19-23.)

Claim 26 recites the method of claim 25 wherein the active ingredient is allyl isothiocyanate. (Page 7, lines 13-14.)

Claim 27 recites the method of claim 26 wherein the compress is soaked in water to activate the active ingredient. (Page 7, lines 1-22.)

Claim 28 recites the method of claim 27 wherein the water is at a temperature of approximately 10°C. (Page 7, line 15.)

Claim 29 recites the method of claim 25 wherein the facial mask is adapted to be secured to a person's head. (Page 6, line 32-page 7, line 3.)

Claim 30 recites the method of claim 13 further comprising the steps of squeezing the compress to force out the active ingredient; opening skin pores to which pressure is applied; forcing the active ingredient through the opened skin pores of a person in the direction of an inflammation. (Page 7, line 31-page 8, line 5.)

## GROUNDS FOR REJECTION TO BE REVIEWED ON APPEAL

Whether claims 13-14, 17-19, 21-26, and 30 are patentable and non-obvious over the combination of GB 2 0880714 to Marinello ("Marinello"), U.S. Patents Nos. 2,262,711 to Ludwin et al. ("Ludwin") and 6,748,949 to Smaldone ("Smaldone").

Whether claims 15, 16, 27, and 28 are patentable and non-obvious over the combination of Marinello with Ludwin and Smaldone, in view of *Flavor pharmaceutical properties of the volatile sulphur compounds of Wasabi* by Depree et al. ("Depree").

Whether claims 20 and 29 are patentable and non-obvious over the combination of Marinello with Ludwin and Smaldone, in view of U.S. Patent No. 5,429,126 to Bracken ("Bracken").

## ARGUMENTS

### I) CLAIMS 13-33 ARE PATENTABLE AND NON-OBVIOUS

#### a) Claims 13-14, 17-19, 21-26, and 30 are patentable over Marinello, Ludwin, and Smaldone

Claims 13-14, 17-19, 21-26, and 30 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of GB 2088714 to Marinello ("Marinello"), U.S. Patents Nos. 2,262,711 to Ludwin ("Ludwin") and 6,748,949 to Smaldone ("Smaldone").

Claims 13 and 25 are independent.

Claims 13 recites, *inter alia*,

> A device comprising a **facial mask** accommodated to allow **unobstructed respiratory function of the nostrils and the mouth**...and a **compress**...said compress comprising...**an active ingredient**, wherein the device promotes the **absorption of the active ingredient through the skin to bones underlying mucous membranes** in a sinus of a person in need thereof.

Emphasis added. Appellants traverse and respectfully request of this Honorable Board for a reversal of the rejection in view of the following remarks.

*i) Marinello fails to disclose **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person** as required by claim 13.*

Marinello is directed to application of a revulsion containing oil of horseradish or oil of mustard in vegetable oil (*Marinello*, page 2, line 123-page 3, line 2) to a cutaneous area of the body to increase the blood circulation to an injury, inflammation or diathesis, the revulsion being applied under pressure (*Id.*, page 3, lines 40-50 as cited by the examiner). The pressure causes

the following effects: (1) squeezing of the dressing and releasing of the revulsion, (2) widening of the pores of the skin, and (3) the penetration of the medicine through the pores near the injured area. *Id.*, Page 3, lines 64-72 as cited by the Examiner. As a result of these effects, "the medicine will in disperse into the blood-stream and in part reach the blood vessels serving the injured, inflamed of diathetic organ. This provokes the enlargement of the vessels, thereby producing an increased flow of blood with curative consequences." *Id.*, page 3, lines 73-80.

Accordingly, the reference teaches only an increased blood flow to an area caused by the application of an oil-based revulsion under pressure. The reference fails to disclose or render predictable **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** as required by the claims. There is no suggestion that the inventive revulsion is capable of reaching bones underlying mucous membranes.

In the response submitted November 23, 2009, Appellants submitted that the oil of horseradish (or oil of mustard) and vegetable oil composition disclosed in the reference is not suitable for **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** as required by the claims. The vegetable oil, because of its characteristic density, is not suitable to penetrate the skin pores to reach the bones and mucous membranes underlying the skin.

Marinello discloses that the "use of vegetable oil solutions...allows the solution to be maintained on the body for a longer period of time, thus allowing the revulsives to enter the dilated pores of the skin and cause reactions in the deep blood vessels of the body underlying the skin to which the solution is applied." *Id.*, page 2, lines 109-115 as cited by the Examiner on pages 4-5 of the Office Action.

The Examiner has not indicated a portion of the reference which suggests **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** as required by the claims. Appellants respectfully submit that there is no such disclosure in the reference.

*ii) Marinello fails to teach a **facial mask** accommodated to allow **unobstructed respiratory function of the nostrils and the mouth***

On page 5 of the Office Action, the Examiner concedes that Marinello doe not explicitly teach the use of a face mask as presently claimed in claims 13 and 25. The Ludwin reference is relied upon for such a teaching. The Examiner characterizes Ludwin as teaching a medical nebulizer for treating sinusitis, the nebulizer comprising a face mask, medicament in a chamber, and pressure provided to vaporize the medicine. Further, the Examiner asserts the medicaments of Ludwin are contained in a sponge member and applied under pressure, specifying that the "pressure under the mask provides efficient delivery of the drugs and allows penetration of the drug into small pores of the sinus tract." Appellants respectfully disagree that such a teaching can be found in Ludwin.

The Examiner also concedes that Ludwin does not explicitly teach the face mask is unobstructive and covers the nose and mouth. Instead, the Examiner relies on Smaldone to teach a face mask for delivering pressurized drugs from a nebulizer, the face mask having openings to release the undesired drug. The openings are alleged to teach unobstructed respiratory function.

**(1) *Prima Facie Obviousness has not been established***

Appellants respectfully submit that the Examiner has not established that the claimed invention was *prima facie* obvious to one of skill in the art at the time of the invention, contrary to the assertions beginning on page 6 of the Office Action.

As presently claimed, the inventive device comprises, inter alia, **a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth ...and a compress...having an active ingredient...**[that] **promotes absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus.**

As discussed above, Marinello discloses the application of an oil-based revulsion to cutaneous tissue to stimulate blood flow to an area. Ludwin and Smaldone teach face masks for medical nebulizers as acknowledged by the Examiner. Accordingly, the Examiner is combining a cutaneous drug application system for stimulating blood flow with an inhaled aerosol drug application system and alleging the combination makes obvious the claimed device that includes a **facial mask**...[that] **promotes absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus.**

Appellants respectfully submit that modifying Marinello by Ludwin alone, or in combination with Smaldone, changes the principle of operation of Marinello and thus fails to support a *prima facie* case of obviousness. As explained at M.P.E.P. §2143.01:

> If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

Modification of Marinello by either Ludwin or Smaldone would change the method of operation from a cutaneous system to an inhaled aerosol system.

Moreover, if Marinello's cutaneous medicament delivery system were modified by the nebulizer system of Ludwin or Smaldone, Marinello would be inoperable for use as a cutaneous medicament delivery system to stimulate blood flow to the area. A proposed modification that renders the prior art invention being modified unsatisfactory for its intended purpose does not support a *prima facie* case of obviousness. As explained at M.P.E.P. §2143.01.

> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

Because the proposed modification of Marinello by Ludwin would render Marinello unsuitable for its intended purpose, there is no support for a *prima facie* case of obviousness.

**(2) *Combining the references fails to teach the present invention.***

In the event combining Marinello with Ludwin and Smaldone is found to be *prima facie* obvious, which Appellants submit is not the case, the combination fails to teach the present invention.

In the first full paragraph on page 6 of the Office Action, the Examiner asserts that it was known to "treat sinusitis by administering dressing impregnated with mustard oil to the skin and using means of inflatable elastic pad to squeeze the revulsive from the compress to the skin." Emphasis added. However, there is no indication in the cited portion that a device or method was disclosed or rendered predictable that promoted **absorption of the active ingredient**

**through the skin to bones underlying mucous membranes in a sinus** as claimed. Marinello discloses only that the inventive solution makes the revulsive power of the oil of mustard or oil of horseradish tolerable to the surface of the body (*Marinello*, page 2, lines 103-108), thereby allowing the revulsive to be maintained on the body for a longer period of time. The result is that the revulsives enter the pores of the skin and cause reactions in the deep blood vessels of the body in the area. *Id.*, lines 109-115. Emphasis added. There is no disclosure of absorption **through the skin to bones underlying mucous membranes** as claimed.

In fact, as Appellants submitted in the November 23, 2009 response, and reiterated above, the solution disclosed in Marinello is not suitable for penetration through the skin and mucous membranes to underlying bones because of the characteristic density of vegetable oil as taught by Marinello hinders such penetration.

Accordingly, Marinello fails to disclose or render predictable **absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus** as claimed.

The second full paragraph on page 6 of the Office Action asserts that Ludwin teaches delivering medicaments to the sinuses using an impregnated dressing and a face mask using pressure. The Examiner goes on to assert in the final paragraph on page 6, carrying over to page 7, that it was "known to use a face mask to cover the impregnated compress as taught by Ludwin."

Appellants submit that there is no such teaching in Ludwin. Initially, "dressing" is not found in the reference or in the claims. Appellants submit that, contrary to the Examiner's assertion, the reference is also silent on a "compress" as required by the claimed, or any similar term for "compress," or any structure which could be used as a compress according to the instant

application. (*See* definition of "compress" at page 3, lines 1-4 of Appellants' Pre Appeal Brief Request for Review of April 29, 2009).

On page 5 of the Office Action, the Examiner recites "medicaments are contained in a sponge member and applied under pressure," citing to column 2, lines 9-12 and column 3, lines 21-23.

Appellants submit the first cited portion of the reference recites, "The device also involves the use of a receptacle for containing a medicament which may be directly applied to the [motor driven rotary] compressor for applying the medicament under pressure."

The latter cited portion, taken with the preceding two lines to provide context, recites, "The device may also be provided with an injector as shown in Figure 5, which is formed with a tubular casing 28, and the medicament may be contained in a sponge member 29 in an inner glass tube 30..." *Ludwin*, column 3, lines 19-23.

Accordingly, neither portion of the reference discloses a "dressing" or a "compress".

Appellant submits a reasonable interpretation is that the recited "sponge member" was intended to be the "dressing" referenced by the Examiner, and "dressing" was intended to be synonymous with the claimed "compress". However, even with this generous interpretation, support for the Examiner's assertion that it was "known to use a face mask to cover the impregnated compress as taught by Ludwin" cannot be found in the reference.

Ludwin does not disclose or render predictable a pad applied with pressure to a part of the body to supply medicine, that is, a "compress" (definition of "compress", page 3, lines 1-4 of Appellants' Pre Appeal Brief). The only part of the Ludwin invention that is in contact with a

part of the body is the resilient contact member 5 of the face mask. There is no disclosure of a compress or any similar element in contact with the user.

Appellants submit that the injector of Figure 5 is an applicator separate from the face mask of the reference. *Ludwin*, column 3, line 35-column 4, line 3. As recited above, and illustrated in Figure 5 of Ludwin, the sponge member is not part of the face mask, it does not come in contact with the user, and therefore cannot be considered a "compress" as required by the claims.

Smaldone is used by the Examiner to teach a face mask for delivering pressurized drugs from a nebulizer, the face mask having openings to release the undesired drug. Appellants submit that a mask having openings to release the undesired drug does not disclose **a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth** as claimed.

The Examiner has noted that Smaldone is directed to a nebulizer having a face mask. Therefore, as first presented in Appellants' November 23, 2009 response, Smaldone contains the same deficiencies as discussed for Ludwin.

Smaldone recites that in related art masks used for drug delivery in a nebulizer or a metered dose inhaler, when a patient wearing the face mask inhales, "a negative pressure is applied to the face mask reservoir and the aerosolized drug is inhaled and enters the respiratory system of the patient." *Smaldone*, column 1, lines 40-43. Smaldone also recites that the inventive mask disclosed is of a similar construction as the related art face masks, with the one exception of a "vent 110 which serves to discharge aerosol." Smaldone, column 7, lines 28-29 and 58-59.

In order for the inhalation of the patient to create a negative pressure within the mask reservoir as taught by Smaldone, some resistance to the inhalation must be created. As the respiratory function is generally understood to include both inhalation and exhalation, restriction of either constitutes obstruction of the respiratory function. Because Smaldone discloses state of the art face masks develop a negative pressure in the face mask reservoir when the wearer inhales, the reference discloses such masks obstruct at least the inhalation portion of the respiratory function. Therefore, contrary to the Examiner's assertion, the mask taught by Smaldone does not disclose or render predictable **a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth** as claimed.

Accordingly, Ludwin and Smaldone, either taken separately or combined, fail to disclose or render predictable **a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth** as claimed. Furthermore, Marinello modified by Ludwin, with or without Smaldone, fails to disclose or render predictable a device comprising a **facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth**...and a **compress** comprising **a revulsive or cress having an active ingredient**, wherein the device promotes the **absorption of the active ingredient through the skin to bones underlying mucous membranes** as claimed.

**b) Claims 15, 16, 27, and 28 are patentable over Marinello, Ludwin and Smaldone, in view of Depree.**

Page 8 of the Office Action concedes that Marinello, Ludwin and Smaldone fail to explicitly teach the use of water and its temperature to activate the revulsive agent as claimed in

claims 15, 16, 27, and 28. The Examiner relies upon Depree to teach the use of water at a particular temperature to activate the revulsive agent, citing to page 333, left column, first paragraph.

The defects in Marinello, Ludwin, and Smaldone are amply discussed above. Accordingly, assuming *arguendo* that the teaching of Depree is as asserted in the Office Action, the disclosure of the reference does not cure the defects found in Marinello, Ludwin, and Smaldone.

Furthermore, Appellants respectfully submit that the cited passage of Depree fail to disclose or render predictable the use of water at a particular temperature to activate the revulsive agent. The passage cited by the Examiner refers to the decomposition of isothiocyanates in water being temperature dependent. The passage is silent on the activation of isothiocyanates when exposed to water at a particular temperature.

The Examiner asserts in the second paragraph on page 9 of the Office Action that it would be obvious to one of ordinary skill in the art to use water between 37°C and above 0°C as taught by Depree to "ensure solubility of the active agent in the solution. Appellants respectfully submit that solubility of isothiocyanates in water is not taught in the cited passage and is different than the decomposition of isothiocyanates that is the subject of the passage.

Accordingly, Marinello, Ludwin, and Smaldone, in view of Depree, fail to teach **a compress is soaked in water to activate the active ingredient** or **wherein the water is at a temperature of approximately 10° C** as required by the claims.

**c) Claims 20 and 29 are patentable over Marinello, Ludwin and Smaldone in view of Bracken.**

On page 10 of the Office Action, the Examiner concedes that Marinello, Ludwin, and Smaldone fail to teach the means for securing the mask to the head as instantly claimed in claims 20 and 29.

The Office Action asserts that Bracken teaches a mask that is secured to a person's head.

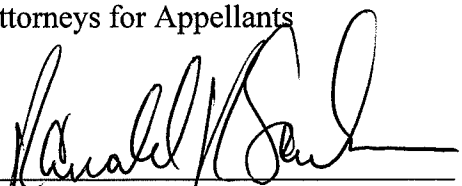
The defects found in Marinello, Ludwin, and Smaldone have been amply discussed above. Assuming arguendo that the teaching of Bracken is as asserted in the Office Action, the reference fails to correct the defects found in Marinello, Ludwin, and Smaldone.

## CONCLUSION

In view of the foregoing remarks, Appellant's attorneys respectfully submit that claims 13-30 are patentable. It is therefore respectfully submitted that the Examiner erredin rejecting claims 13-30, and Appellants request a reversal of these rejections by this Honorable Board. As a result, the allowance of this application should be mandated.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Appellants

By: 

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## APPENDIX I

## CLAIMS ON APPEAL

1. (Withdrawn) A device comprising a facial mask, an inflatable elastic pad affixed to the mask and a compress containing a revulsive or cress having an active ingredient.

2. (Withdrawn) The device according to claim 1, wherein the active ingredient is allyl isothiocyanate.

3. (Withdrawn) The device according to claim 2, wherein the compress is soaked in water to activate the active ingredient.

4. (Withdrawn) The device according to claim 3, wherein the water is at a temperature of approximately 10° C.

5. (Withdrawn) The device according to claim 1, wherein the inflatable elastic pad comprises a first membrane and a second membrane.

6. (Withdrawn) The device according to claim 5, wherein the first membrane and the second membrane form a compression chamber.

7. (Withdrawn) The device according to claim 6, wherein a pump is used to inflate the compression chamber.

8. (Withdrawn) The device according to claim 1, wherein the facial mask comprises at least one opening and means for securing the facial mask to a person's head.

9. (Withdrawn) The device according to claim 1, wherein the facial mask covers the upper part of a person's head.

10. (Withdrawn) The device according to claim 1, wherein the facial mask covers the lower part of a person's head.

11. (Withdrawn) The device according to claim 1, wherein the facial mask is adapted to allow respiration.

12. (Withdrawn) The device according to claim 1, wherein the facial mask comprises plastic adapted to be resistant to deformation.

13. (Previously Presented) A device comprising a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth, an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient, wherein the device

promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof.

14. (Original) The device according to claim 13, wherein the active ingredient is allyl isothiocyanate.

15. (Original) The device according to claim 13, wherein the compress is soaked in water to activate the active ingredient.

16. (Original) The device according to claim 15, wherein the water is at a temperature of approximately 10° C.

17. (Original) The device according to claim 13, wherein the inflatable elastic pad comprises a first membrane and a second membrane.

18. (Original) The device according to claim 17, wherein the first membrane and the second membrane form a compression chamber.

19. (Previously Presented) The device according to claim 18, wherein a rubber pump is used to inflate the inflatable elastic pad.

20. (Original) The device according to claim 13, wherein the facial mask comprises at least one opening and a means for securing the facial mask to a person's head.

21. (Original) The device according to claim 13, wherein the facial mask covers an upper part of a person's head.

22. (Original) The device according to claim 13, wherein the facial mask covers the lower part of a person's head.

23. (Original) The device according to claim 13, wherein the facial mask is adapted to allow respiration.

24. (Previously Presented) The device according to claim 13, wherein the facial mask is made of plastic adapted to be resistant to deformation.

25. (Previously Presented) A method of treating sinusitis comprising the step of securing a device to a person's head, the device comprising a facial mask accommodated to allow unobstructed respiratory function of the nostrils and the mouth, an inflatable elastic pad affixed to the facial mask and a compress fitted adjacent to said inflatable elastic pad, said compress comprising a revulsive or cress having an active ingredient wherein the device promotes the absorption of the active ingredient through the skin to bones underlying mucous membranes in a sinus of a person in need thereof.

26. (Original) The method according to claim 25, wherein the active ingredient is allyl isothiocyanate.

27. (Original) The method according to claim 26, wherein the compress is soaked in water to activate the active ingredient.

28. (Original) The method according to claim 27, wherein the water is at a temperature of approximately 10° C.

29. (Original) The method according to claim 25, wherein the facial mask is adapted to be secured to a person's head.

30. (Original) The method according to claim 25, further comprising the steps of squeezing the compress to force out the active ingredient; opening skin pores to which pressure is applied; and forcing the active ingredient through the opened skin pores of a person in the direction of an inflammation.

31. (Withdrawn) A method of using a revulsive having an active ingredient to treat inflammation comprising the steps of:

providing a revulsive or cress in a dried form;

soaking the revulsive or cress to activate the active ingredient; and

squeezing the revulsive or cress to force out the active ingredient onto a portion of a person's skin to reduce inflammation.

32. (Withdrawn) The method according to claim 29, wherein the active ingredient is allyl isothiocyanate.

33. (Withdrawn) A compress containing an active ingredient in a dried form compressing allyl isothiocyanate which is activated upon the application of water.

## APPENDIX II

## EVIDENCE

None

## APPENDIX III

## RELATED PROCEEDINGS

None